

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 28419	FOR FURTHER ACTION See item 4 below	
International application No. PCT/IL2004/001129	International filing date (<i>day/month/year</i>) 15 December 2004 (15.12.2004)	Priority date (<i>day/month/year</i>) 15 December 2003 (15.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant TECHNION RESEARCH & DEVELOPMENT FOUNDATION LTD.		

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
- This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colomettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 Form PCT/TB/373 (January 2004)	Date of issuance of this report 20 June 2006 (20.06.2006)
	Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30

From the
INTERNATIONAL SEARCHING AUTHORITY

PATENT COOPERATION TREATY

To:
G.E. EHRLICH
G. E. EHRLICH (1995) LTD.
11 MENACHEM BEGIN STREET
52 521 RAMAT-GAN
ISRAEL

REC'D 08 DEC 2005

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

05 DEC 2005

Applicant's or agent's file reference

28419

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IL04/01129

International filing date (day/month/year)

15 December 2004 (15.12.2004)

Priority date (day/month/year)

15 December 2003 (15.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 2/06 and US Cl.: 623/1.11, 1.13, 1.42, 1.44; 606/194

Applicant

TECHNION RESEARCH & DEVELOPMENT FOUNDATION LTD.

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

04 November 2005 (04.11.2005)

Authorized officer

Sarah K. Webb

Telephone No. (703) 308-0858

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL04/01129

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims Please See Continuation Sheet YES
Claims Please See Continuation Sheet NO

Inventive step (IS)

Claims Please See Continuation Sheet YES
Claims Please See Continuation Sheet NO

Industrial applicability (IA)

Claims Please See Continuation Sheet YES
Claims Please See Continuation Sheet NO

2. Citations and explanations:

Claims 1-9, 16, 17, 22-34, 41, 42, 47-59, 66, 67, 72-75, 111-118, 125, 126, 131-133 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,637,113 to Tartaglia et al. Tartaglia discloses a stent (22) with a rolled bioabsorbable film (24) wrapped around it. The stent can be delivered by a balloon catheter, as shown in Figure 15. The stent can be either self-expanding or balloon expandable (column 5, lines 18-48). The film is loaded or coated with various types of drugs, such as heparin (column 5, line 49 through column 6). The film can include a lubricious coating that includes polyethylene glycol (PEG) (column 9, lines 20-35).

Claims 76-90 and 97-104 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,550,178 to Desai et al. Desai discloses a biocompatible film that comprises PEG and alginate. Desai states that the film is used to deliver drugs at a controlled rate (column 3, lines 45-50; column 4, lines 50-56). The PEG can be PEG-DA (column 6, line 59). The concentration of alginate and the ratio of PEG to alginate can vary widely (column 5, lines 14-24; column 6, lines 51-67). In Example 5, calcium chloride is contained in the PEG/alginate material, and the alginate is sodium alginate.

Claims 10-15, 35-40, 60-65, 95, 96, 109, 110, and 119-124 lack an inventive step under PCT Article 33(3) as being obvious over Tartaglia et al. in view of Desai et al. Tartaglia fails to form the lubricious coating from a PEG/alginate material. Desai teaches that a PEG/alginate coating should be used to deliver drugs at a controlled rate, because the material is highly biocompatible, chemically and mechanically stable, and prevents migration of molecules through the material that are harmful to the encapsulated drug (column 3, lines 27-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a PEG/alginate material in the Tartaglia film, as Desai teaches that this substance is highly advantageous for controlled release of drugs.

Claims 18-21, 43-46, 68-71, 91-94, 105-108, 127-130 lack an inventive step under PCT Article 33(3) as being obvious over Tartaglia and Desai in view of US Patent No. 6,379,382 to Yang. Tartaglia and Desai fail to include the specific drugs as set forth in the these claims, but Yang teaches that these substances are known to be helpful in treating vascular diseases when coated on a stent. Lines 1-12 of column 4 include sirolimus, tranilast, and VEGF. Tartaglia teaches that any therapeutic substance not disclosed may be used (column 6, lines 23-25), so it would be obvious to use any of the cytokines set forth in the claims.

Claims 1-133 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL04/01129

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 10-15, 18-21, 35-40, 43-46, 60-65, 68-71, 91-96, 105-110, 119-124, 127-130

The opinion as to Novelty was negative (No) with respect to claims 1-9, 16, 17, 22-34, 41, 42, 47-59, 66, 67, 72-90, 97-104, 111-118, 125, 126, 131-133

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-133

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-133

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE